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(54) **LIGATING BAND WITH ROUNDED EDGES AND ITS METHOD OF MANUFACTURE**

LIGATIONSBAND MIT ABGERUNDETEN KANTEN UND VERFAHREN ZUR DESSEN
HERSTELLUNG

BANDE DE LIGATURE A BORDS ARRONDIS ET SON PROCEDE DE FABRICATION

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Description**Field of the Invention**

[0001] The invention relates generally to the field of tissue ligation, and more particularly to an improved ligating band and a method of making the ligating band.

Background of the Invention

[0002] Physicians have used elastic ligating bands to treat lesions, including internal hemorrhoids and mucositis and for performing mechanical hemostasis.

[0003] The object of ligation is to position a ligating band over the targeted lesion or blood vessel section by stretching the band beyond its undeformed diameter drawing the tissue to be ligated within the band and then releasing the band so that it contracts, applying inward pressure on the section of tissue caught within the band. The effect of the inward pressure applied by the band is to stop all circulation through the targeted tissue, thereby causing the tissue to die. The body then sloughs off the dead tissue or the dead tissue may be aspirated into an endoscope or a similar device.

[0004] Ligating bands are typically dispensed using ligating band dispensing devices which include cylindrical support surfaces over which elastic ligating bands are stretched. The cylindrical support surfaces are typically attached to the distal end of an endoscope which is advanced into the body to a target area. A user then applies suction through the endoscope to draw the tissue to be ligated into the cylindrical support surface and then releases a ligating band to contract around the tissue.

[0005] Some ligating band dispensers use trigger lines received in slots at the distal end of a cylindrical support to roll ligating bands toward, and eventually off, the distal end of the support. A problem encountered with such devices when dispensing prior ligating bands is the bands may sometimes slide, rather than roll, along the cylindrical support. A band which slides, rather than rolls, may tend to push the trigger line ahead of it. This is disadvantageous because the trigger line may be pushed out of its slot in the distal rim of the cylindrical support, leaving a band with no trigger line attached.

[0006] Ligating bands are often made by extruding an elastic compound through a tubular die. Then tube is then cut transversely to form the bands. As a result of this process, the bands have sharp edges along both the inner and the outer diameter surfaces. Such sharp edges may cause the bands to disadvantageously slide, rather than roll, when being dispensed from devices employing a trigger line.

[0007] United States Patent No. 5,356,416 to Chu et al. and United States Patent No. 5,398,844 to Zaslavsky et al., describe other types of ligating band dispensing devices which include cylindrical support surfaces over which elastic ligating bands are stretched.

[0008] Elastic rings are known from US Patent 1,683,119 to Ziegler, GB 649 226 A to Montgomery and U.S. Patent 5,624,453 to Ahmed.

[0009] A problem inherent with the type of ligating bands typically used with the above-described devices is that the bands have a tendency to slip off the targeted tissue before the tissue is completely ligated. One reason why a ligating band may slip off targeted tissue is because tissue contained within a ligating band is effectively "pinched" by the ligating band, creating an outward pressure on the band. Specifically, the bulb-shaped projection of tissue which has been drawn under suction into the lumen of a cylindrical support surface is pulled away from the surrounding tissue creating tension within the projection which draws the tissue of the projection back toward its natural position. Thus, the tissue is urged to slip out of the ligating band as the band contracts. In addition, blood and fluid within the body can make the surface of the targeted tissue slick, thereby decreasing the coefficient of friction between the ligating band and the targeted tissue. Also, if the targeted tissue is an active blood vessel the "pulsing" effect of blood moving through the vessel can cause the ligating band to slip off of the targeted tissue.

[0010] Therefore, what is needed is a ligating band which rolls, rather than slides, as it moves toward the distal end of the dispenser housing in trigger line-type dispensers. Also what is needed is a ligating band which remains in place once dispensed onto the target tissue.

Summary of the Invention

[0011] The present invention is directed to an improved elastic band for ligating tissue within a living body comprising a central opening defining an axis and having a first curved edge formed between a first surface extending substantially parallel to the axis and a second surface extending substantially perpendicular to the axis.

[0012] A method of ligating tissue within a living body using such a ligating band comprises the steps of positioning the elastic band, which has been stretched to increase the size of a central opening extending therethrough, adjacent to a portion of tissue to be ligated. The tissue to be ligated is then drawn through the central opening of the elastic band and the elastic band is released so that the size of the central opening decreases to grip the tissue received therein.

Brief Description of the Drawings

[0013] The invention will be more readily understood through the following detailed description, with reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of a ligating band according to a preferred embodiment of the present invention;

Fig. 2 is an axial cross-sectional view of the ligating band shown in Fig. 1;

Fig. 3 is a perspective view of a ligating band according to the prior art;

Fig. 4 is a cross-sectional view of the ligating band shown in Fig. 3;

Fig. 5 is a side elevational view in partial cross-section of a prior ligating band dispenser which may be used to dispense a ligating band of the present invention;

Fig. 6 is a perspective view of a ligating band according to a second embodiment of the present invention having textured surfaces;

Fig. 7 is a cross-sectional view of the ligating band shown in Fig. 6;

Fig. 8 is a perspective view of a portion of tissue drawn into a device for applying elastic ligating bands;

Fig. 9 is a perspective view of a portion of tissue with an elastic ligating band received thereon.

Description of the Preferred Embodiment

[0014] A preferred embodiment of the invention is illustrated in Figs. 1 and 2 as ligating band 1. As embodied herein, ligating band 1 is formed as a ring comprising inner surface 2, outer surface 4, first side surface 6, second side surface 8 and central opening 11 through defining an axis 21. Of course, those skilled in the art will understand that during manipulation, the ligating band 1 may be intentionally or accidentally twisted so that any of the surfaces 4, 6 and 8 becomes the inner surface 2. As embodied herein, surfaces 2 and 6 meet at edge, or juncture, 12. Likewise, surfaces 2 and 8 meet at edge 14, surfaces 4 and 6 meet at edge 16, and surfaces 4 and 8 meet at edge 18. As indicated in Fig. 2, as embodied herein, ligating band 1 has an inner diameter ID, an outer diameter OD, and an axial thickness AT.

[0015] As embodied herein, the inner diameter ID of ligating band 1 is between 0.178 and 0.216 centimeters (0.07 and 0.085 inches) and is more preferably between 0.178 and 0.203 centimeters (0.07 and 0.08 inches) and is most preferably approximately 0.19 centimeters (0.075 inches). The outer diameter OD of the band is preferably between 0.558 and 0.610 centimeters (0.22 and 0.24 inches), while the band preferably has an axial thickness AT of approximately 0.178 and 0.216 centimeters (0.07 and 0.085 inches), is more preferably between 0.178 and 0.203 centimeters (0.07 inches and 0.08 inches) and is most preferably approximately 0.19 centimeters (0.075 inches). Of course, those skilled in

the art will recognize that such a ligating band may easily be rolled across the cylindrical support surface so that the ID surface becomes the OD surface, etc. and that it may therefore be preferable to make the thickness of 5 the band 1 in each direction between 0.178 and 0.216 centimeters (0.07 and 0.085 inches), more preferably between 0.178 and 0.203 centimeters (0.07 inches and 0.08) inches and most preferably approximately 0.19 centimeters (0.075 inches) so that the cross-section of 10 the band 1 is substantially square (except for the rounded edges).

[0016] As embodied herein, inner surface 2 is preferably substantially parallel to outer surface 4, while first side surface 6 is preferable substantially parallel to second side surface 8, so that ligating band 1 has an axial cross-section which is substantially rectangular. In other embodiments of the invention, surfaces 2 and 4, or 6 and 8, respectively, may be non-parallel to each other so that ligating band 1 has an axial cross-section which 15 is a trapezoid, an irregular quadrilateral, etc. In other embodiments of the invention ligating band 1 may have only three surfaces forming a triangular cross-section. In other embodiments of the invention, one or both of the surfaces 6 and 8 themselves may be rounded such 20 that surfaces 2, 4, 6 and 8 form a continuous surface having an elliptical or other correspondingly curved cross-section.

[0017] Referring again to Fig. 2, as embodied herein, edges 12, 14, 16 and 18 of ligating band 1 are curved, 30 or radiused, so that ligating band 1 may roll when being advanced along a cylindrical support in a ligating band dispenser. Curved edges 12, 14, 16 and 18 may thus avoid the tendency to slide, rather than roll, exhibited by prior ligating bands having sharp edges. As embodied 35 herein the radius of curvature of curved edges 12, 14, 16 and 18 is approximately 0.038 cm (0.015 in) for a band having the preferred dimensions described above. In other embodiments of the invention, the radius of curvature of curved edges 12, 14, 16 and 18 may have other 40 appropriate magnitudes apparent to those skilled in the art.

[0018] As embodied herein, ligating band 1 is made of from latex. In other embodiments of the invention, ligating band 1 may be made of polyisoprene or any of a 45 variety of other elastic materials. Ligating band 1 is preferably formed by any of a variety of known molding processes such as those in which a material is injected into a mold and cured to form an elastic band of the desired shape and size. In other embodiments of the invention, 50 other band formation techniques known in the art may be employed.

[0019] Referring now to Figs. 6 and 7, in an alternate embodiment of the invention, ligating band 1 is provided with texturing 50, of the type described in US. Patent 55 No. 5,976,158. Texturing 50 provides enhanced gripping of the tissue held by ligating band 1.

[0020] As embodied herein, texturing 50 is provided on each surface 2, 4, 6 and 8. In other embodiments, tex-

turing 50 may be provided on all or some of the surfaces of any of the improved ligating band 1 embodiments described herein. Those skilled in the art will recognize that one or both of surfaces 6, or 8 may be rounded, as described above, reducing the distinction between the various surfaces. However, this distinction between the various surfaces is unimportant so long as the surface of the ligating band 1 which is in contact with the tissue to be ligated includes texturing as described herein.

[0021] As shown in Fig. 6, the texturing 50 is preferably comprised of a pattern of raised bumps which are formed as cylindrical stems 52 and hemispherical caps 54. In other embodiments of the invention, texturing 50 may comprise other types of discontinuities such as depressions, or both raised bumps and depressions. Alternate forms of texturing 50 can employ one or more of a variety of different shapes. On any surface 2, 4, 6 or 8 to which the texturing 50 is applied, the texturing 50 is preferably evenly distributed.

[0022] The texturing 50 may preferably be applied to the ligating band 1 via a molding process, thereby making the texturing 50 an integral part of the structure of the ligating band 1. Preferably, the texturing 50 is formed from the same material as the band itself.

[0023] As embodied herein, texturing 50 is applied to the ligating band 1 so that the raised bumps on a first side 18 of the inner surface 2 and the raised bumps on a second side 20 thereof combine to form an interlocking pattern. By interlocking those skilled in the art will understand that the raised bumps on both the first side 19 and the second side 20 hold the tissue to be ligated by the ligating band 1 more securely in place when the ligating band 1 applies inward pressure on the tissue with the bumps from one side forcing the tissue into a gap between the bumps on the other side.

[0024] With further reference to Fig. 6, although it is preferable to have texturing 50 on all surfaces 2, 4, 6 and 8 of the ligating band 1, it is not necessarily required so long as the user ensures that the surface including the texturing 50 remains, through the placement procedure, positioned so that it contacts the surface to be ligated. In use, the tissue to be ligated is drawn up within central opening 11. Thus, only texturing 50 placed on the surface positioned at inner surface 2 is designed to come in contact with the tissue to be ligated.

[0025] However, it is preferred that texturing 50 be provided on each of surfaces 4, 6 and 8 in addition to inner surface 2 as the ligating band 1 may "roll" after during the dispensing procedure or after being dispensed onto the tissue to be ligated. Thus, a physician cannot be certain that the ligating band 1 will not ultimately be turned "inside out" on the tissue to be ligated such that outer surface 4, for example, comes in contact with the tissue to be ligated rather than the inner surface 2.

[0026] As shown in Figs. 8 and 9, to apply ligating band 1 a physician first loads the band onto cylindrical support 32 of a ligating band dispenser 30, such as a

trigger line ligating dispenser described above or such as a dispenser described in U.S. Patent No. 5,356,416, so that the inner diameter ID of the ligating band 1 is substantially greater than its natural, pre-deformed inner diameter ID.

[0027] Next the physician positions distal end 34 having distal aperture 36 of the ligating band dispenser 30 adjacent to a first portion 38 of tissue T1. The first portion 38 is then drawn into the distal aperture 36, preferably under suction. Alternatively, the first section of tissue T1 may be drawn within the distal aperture 36 by mechanical means, such as a forceps, jaws, clamp, or the like (not shown). The physician then triggers the ligating band dispenser 30 to release one or more ligating bands 1 off of distal end 34 over the targeted first portion 38 of tissue T1.

[0028] As seen in Fig. 9, when the ligating band 1 has been dispensed from the ligating band dispenser 30, the inner diameter ID of the ligating band 1 suddenly decreases as the ligating band 1 seeks to return to its pre-deformed state. As the inner diameter ID decreases, the texturing 50 on the inner surface 2 of the ligating band 1 engages first portion 38 of tissue T1 and exerts inward pressure on the tissue. In embodiments of the invention having texturing 50 on inner surface 2, the texturing provides additional grip for engaging tissue T1. The pressure on the tissue stops all circulation through the targeted tissue T1, thereby causing first portion 38 to die. The body then sloughs off the dead tissue 38. Alternatively, the dead tissue 38 may be removed by mechanical means and aspirated into an endoscope, the ligating band dispenser 30, or a similar device.

[0029] In embodiments of the invention having texturing 50, while the texturing 50 on the inner surface 2 of the ligating band 1 is exerting inward pressure on the tissue 36, the texturing 50 restricts the movement of the ligating band 1 over the tissue 36. Thus, the ligating band 1 of the present invention is less likely than prior art ligating bands to be displaced from the targeted tissue portion 38 in response to outward pressures caused by the "pinching" of the targeted tissue portion 38 or by the movement of blood or other fluid through the targeted tissue T1. In addition, when the texturing 50 on the inner surface 2 of the ligating band 1 is exerting inward pressure on tissue portion 38, it is preferable that the texturing 50 on the first side 18 of the inner surface 2 remotely engages the texturing 50 on the second side 20 of the inner surface 2 through tissue portion 38 to form an interlocking pattern. By forming such an interlocking pattern, the texturing 50 more effectively restricts the movement of the ligating band 1 relative to tissue portion 38.

[0030] Still other objects and advantages of the present invention will become readily apparent to those skilled in the art from the detailed description, wherein the preferred embodiment and several alternate embodiments of the invention have been shown and described. The description of the preferred embodiment is simply

by way of illustration of the best mode contemplated for carrying out the invention. As will be realized, the invention is capable of other and different embodiments, and its several details are capable of modification in various respects, all without departing from the invention. Accordingly, the drawings and descriptions are to be regarded as illustrative in nature, and not as restrictive of the invention which is to be limited only by the claims appended hereto.

Claims

1. An elastic band (1) for ligating tissue within a living body comprising a central opening defining an axis (21),
characterized in that
 the central opening in the ligating band includes a first curved edge (12) formed between a first surface (2) extending substantially parallel to the axis (21) and a second surface (6) extending substantially perpendicular to the axis (21).
2. The elastic band (1) of claim 1, wherein the first surface (2) includes a plurality of projections (10, 110) formed therein.
3. The elastic band (1) of claim 1, wherein the first surface includes a plurality of depressions formed therein.
4. The elastic band (1) of claim 1, wherein the elastic band (1) is formed substantially in the shape of a cylinder, the band further comprising a second curved edge (14) formed between the first surface (2) and a third surface (8) extending substantially perpendicular to the axis (21), a third curved edge (16) formed between a fourth surface (4) extending substantially parallel to the axis (21) and the second surface (6) and a fourth curved edge (18) formed between the third surface (8) and the fourth surface (4).
5. The elastic band (1) of claim 4, wherein at least one of the first (2), the second (6), third (8) and fourth (4) surfaces includes a plurality of projections (10, 110) extending therefrom.
6. The elastic band (1) of claim 4, wherein at least one of the first (2), second (6), third (8) and fourth (4) surfaces includes a plurality of indentations formed therein.
7. The elastic band (1) of claim 1, wherein a cross section of the band (1) in a direction substantially parallel to the axis (21) is substantially rectangular.
8. A method of making an elastic band (1) for ligating

tissue within a living body, (21) comprising the steps of:

- 5 injecting an elastic material into a mold defining the elastic band, the elastic band (1) comprising a central opening defining an axis where the central opening in the ligating band includes a first curved edge (12) formed between a first surface (2) extending substantially parallel to the axis (21) and a second surface (6) extending substantially perpendicular to the axis (21); and
 curing the material.
- 10 9. The method according to claim 8, wherein a plurality of indentations are formed in a surface of the mold corresponding to the first surface (2) of the elastic band (1), so that the elastic band (1) includes a plurality of projections (10, 110) extending therefrom.
- 15 10. The method according to claim 8, wherein a plurality of projections (10, 110) extend from a surface of the mold corresponding to a first surface (2) of the elastic band (1), so that the elastic band (10) includes a plurality of indentations thereon.
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Patentansprüche

- 30 1. Elastisches Band (1) zum Abbinden von Gewebe innerhalb eines lebenden Körpers, das eine zentrale Öffnung aufweist, welche eine Achse (21) vorgibt, **dadurch gekennzeichnet, dass** die zentrale Öffnung im Ligationsband eine erste gekrümmte Kante (12) enthält, die zwischen einer ersten Oberfläche (2), welche sich im Wesentlichen parallel zur Achse (21) erstreckt, und einer zweiten Oberfläche (6), die sich im Wesentlichen senkrecht zur Achse (21) erstreckt, gebildet wird.
- 35 2. Elastisches Band (1) nach Anspruch 1, worin die erste Oberfläche (2) eine Vielzahl von Vorsprüngen (10, 110) enthält, die darin gebildet werden.
- 40 3. Elastisches Band (1) nach Anspruch 1, worin die erste Oberfläche eine Vielzahl von Vertiefungen enthält, die darin gebildet werden.
- 45 4. Elastisches Band (1) nach Anspruch 1, worin das elastische Band (1) im Wesentlichen in der Gestalt eines Zylinders geformt wird, wobei das Band ferner eine zweite gekrümmte Kante (14) aufweist, die zwischen der ersten Oberfläche (2) und einer dritten Oberfläche (8), die sich im Wesentlichen senkrecht zur Achse (21) erstreckt, gebildet wird, eine dritte gekrümmte Kante (16), die zwischen einer vierten Oberfläche (4), die sich im Wesentlichen parallel zur Achse (21) erstreckt, und der zweiten
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Oberfläche (6) gebildet wird, und eine vierte gekrümmte Kante (18), die zwischen der dritten Oberfläche (8) und der vierten Oberfläche (4) gebildet wird.

5. Elastisches Band (1) nach Anspruch 4, worin wenigstens eine der ersten (2) der zweiten (6), dritten (8) und vierten (4) Oberflächen eine Vielzahl von Vorsprüngen (10, 110) enthält, die sich davon erstrecken.

10. Elastisches Band (1) nach Anspruch 4, worin wenigstens eine der ersten (2), zweiten (6), dritten (8) und vierten (4) Oberflächen eine Vielzahl von Einbuchtungen enthält, die sich darin ausbilden.

15. Elastisches Band (1) nach Anspruch 1, worin ein Querschnitt des Bandes (1) in einer Richtung im Wesentlichen parallel zur Achse (21) im Wesentlichen rechteckig ist.

20. Verfahren zur Herstellung eines elastischen Bandes (1) zum Abbinden von Gewebe innerhalb eines lebenden Körpers, umfassend die Schritte von:

25. Injizieren von elastischem Material in eine Gießform, die das elastische Band vorgibt, wobei das elastische Band (1) eine zentrale Öffnung aufweist, welche eine Achse (21) vorgibt, wobei die zentrale Öffnung im Ligationsband eine erste gekrümmte Kante (12) enthält, die zwischen einer ersten Oberfläche (2), die sich im Wesentlichen parallel zur Achse (21) erstreckt, und einer zweiten Oberfläche (6), die sich im Wesentlichen senkrecht zur Achse (21) erstreckt, gebildet wird; und Aushärten des Materials.

30. Verfahren nach Anspruch 8, worin eine Vielzahl von Einbuchtungen in einer Oberfläche der Gießform gebildet werden, die der ersten Oberfläche (2) des elastischen Bandes (1) entspricht, so dass das elastische Band (1) eine Vielzahl von Vorsprüngen (10, 110) aufweist, die sich davon erstrecken.

35. Verfahren nach Anspruch 8, worin sich eine Vielzahl von Vorsprüngen (10, 110) von einer Oberfläche der Gießform erstrecken, die einer ersten Oberfläche (2) des elastischen Bandes (1) entspricht, so dass das elastische Band (10) eine Vielzahl von Einbuchtungen darauf enthält.

40. Revendications

1. Bande élastique (1) pour ligaturer un tissu dans un corps vivant, comprenant une ouverture centrale définissant un axe (21),

45. caractérisée en ce que l'ouverture centrale dans la bande de ligature comprend un premier bord courbé (12) formé entre une première surface (2) s'étendant essentiellement parallèlement à l'axe (21) et une deuxième surface (6) s'étendant essentiellement perpendiculairement à l'axe (21).

50. 2. Bande élastique (1) selon la revendication 1, dans laquelle la première surface (2) comprend une pluralité de projections (10, 110) formées à l'intérieur.

55. 3. Bande élastique (1) selon la revendication 1, dans laquelle la première surface comprend une pluralité de dépressions formées à l'intérieur.

4. Bande élastique selon la revendication (1), dans laquelle la bande élastique (1) est formée essentiellement dans la forme d'un cylindre, la bande comprenant en outre un deuxième bord courbé (14) formé entre la première surface (2) et une troisième surface (8) s'étendant essentiellement perpendiculairement à l'axe (21), un troisième bord courbé (16) formé entre une quatrième surface (4) s'étendant essentiellement parallèlement à l'axe (21) et la deuxième surface (6) et un quatrième bord courbé (18) formé entre la troisième surface (8) et la quatrième surface (4).

50. 5. Bande élastique (1) selon la revendication 4, dans laquelle au moins une des première (2) deuxième (6), troisième (8) et quatrième (4) surfaces comprend une pluralité de projections (10, 110) s'étendant à partir de celles-ci.

55. 6. Bande élastique (1) selon la revendication 4, dans laquelle au moins une parmi les première (2), deuxième (6), troisième (8) et quatrième (4) surfaces comprend une pluralité d'indentations formées à l'intérieur.

60. 7. Bande élastique (1) selon la revendication 1, dans laquelle une section transversale, de la bande (1) dans une direction essentiellement parallèle à l'axe (21) est essentiellement rectangulaire.

65. 8. Procédé de fabrication d'une bande élastique (1) pour ligaturer un tissu dans un corps vivant, comprenant les étapes de :

70. injection d'un matériau élastique dans un moule définissant la bande élastique, la bande élastique (1) comprenant une ouverture centrale définissant un axe (21), où l'ouverture centrale dans la bande de ligature comprend un premier bord courbé (12) formé entre une première surface (1) s'étendant essentiellement parallèlement à l'axe (21) et une deuxième surface (6)

s'étendant essentiellement perpendiculairement à l'axe (21) ; et durcissement du matériau.

9. Procédé selon la revendication 8, dans lequel une pluralité d'indentations sont formées dans une surface du moule correspondant à la première surface (2) de la bande élastique (1), de sorte que la bande élastique (1) comprend une pluralité de projections (10, 110) s'étendant à partir de celle-ci. 5

10. Procédé selon la revendication 8, dans lequel une pluralité de projections (10, 110) s'étendent d'une surface du moule correspondant à une première surface (2) de la bande élastique (1), de sorte que la bande élastique (10) comprend une pluralité d'indentations dessus. 15

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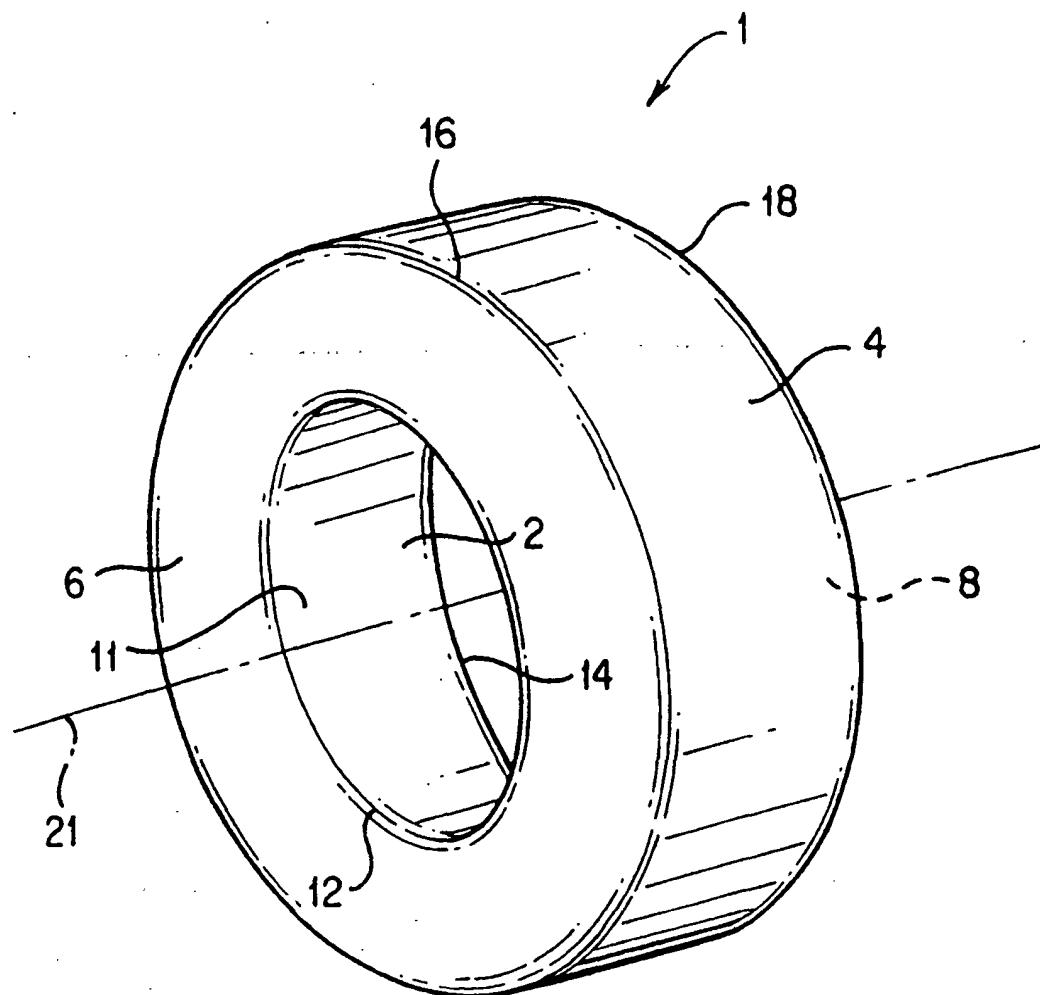


FIG. 1

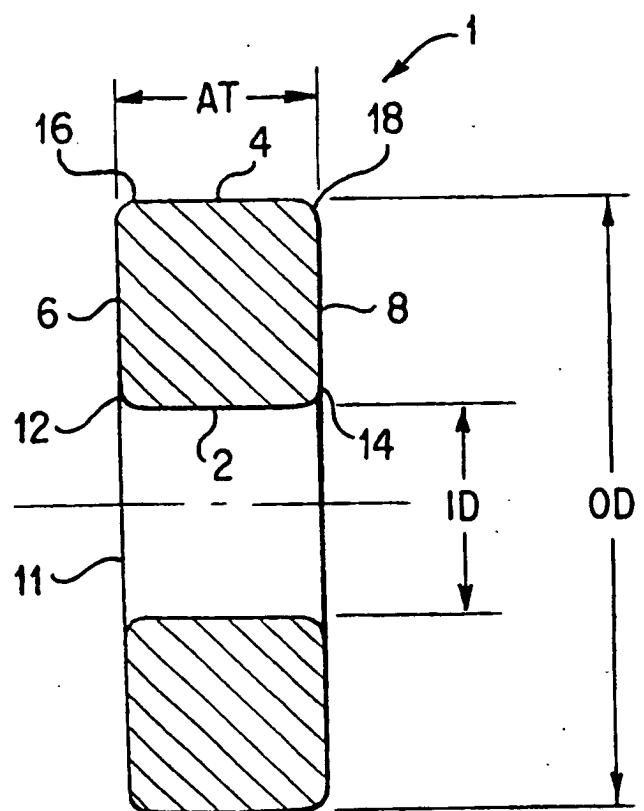


FIG. 2

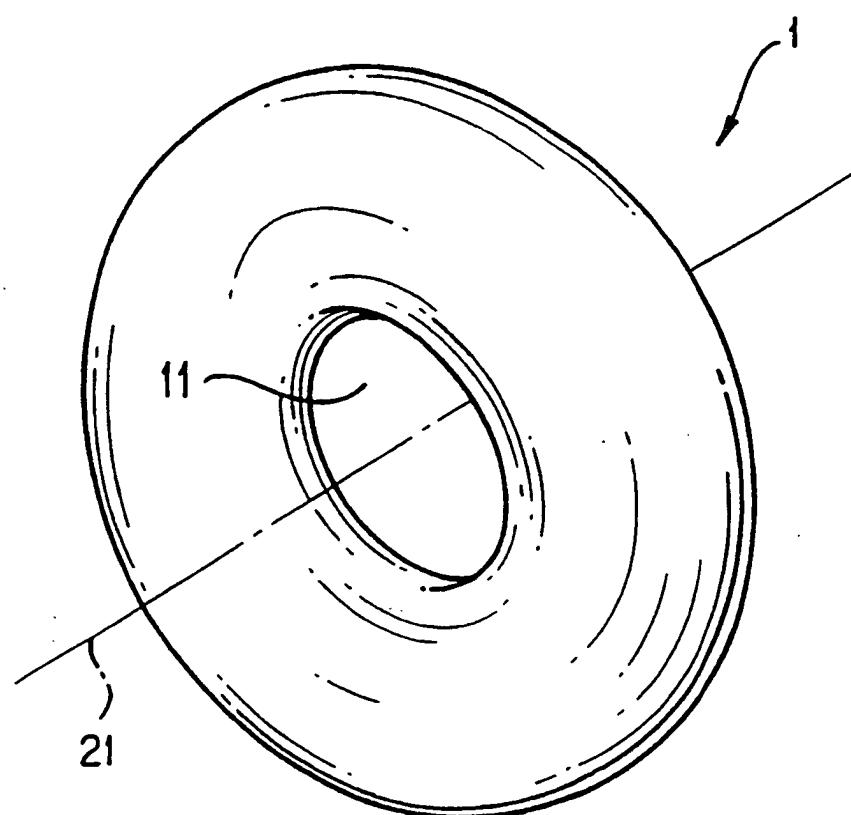


FIG. 3

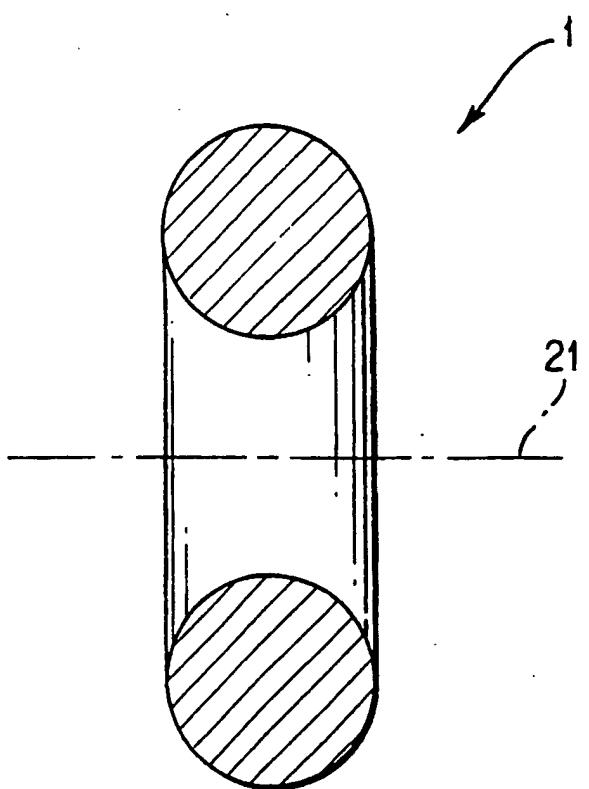


FIG. 4

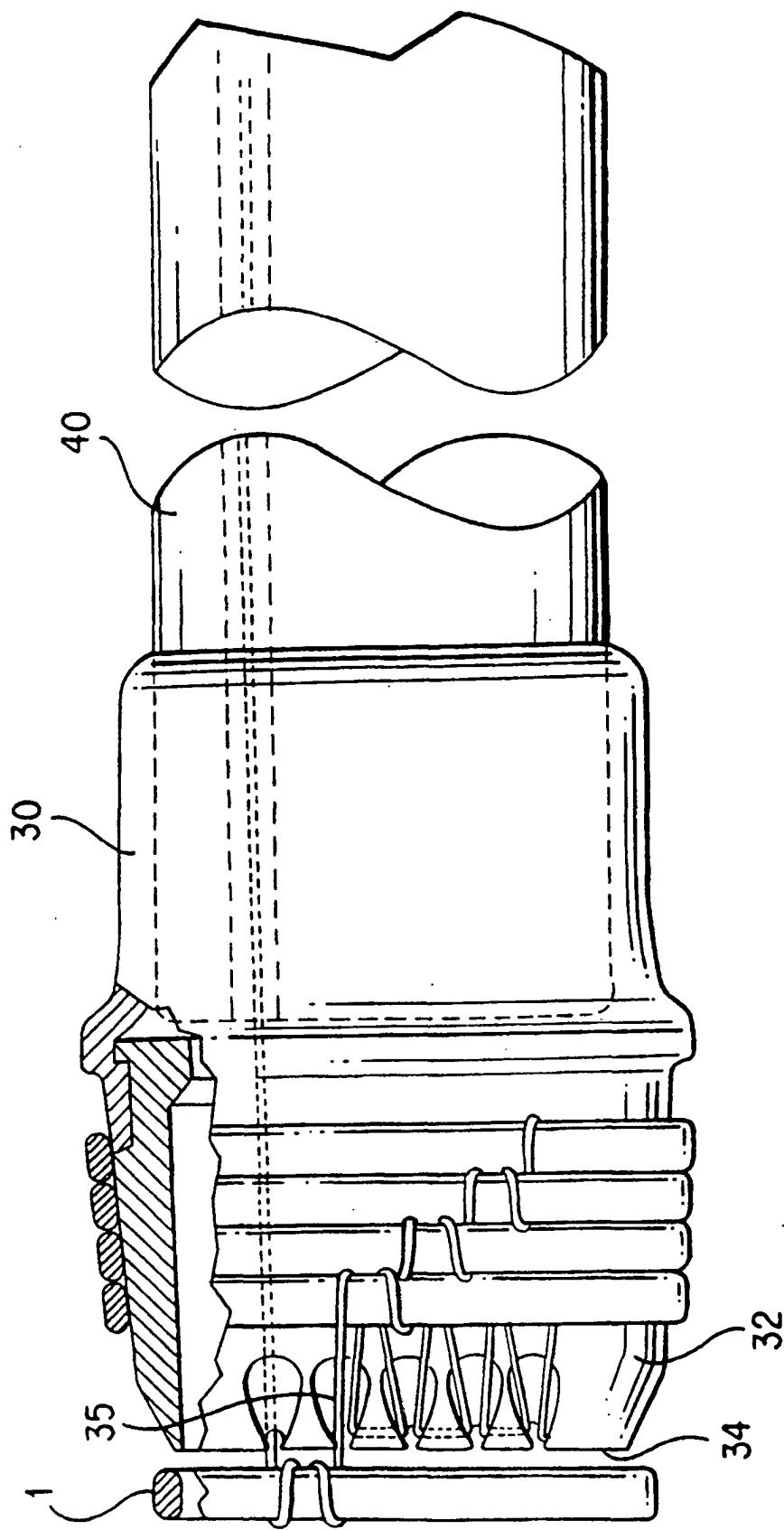


FIG. 5

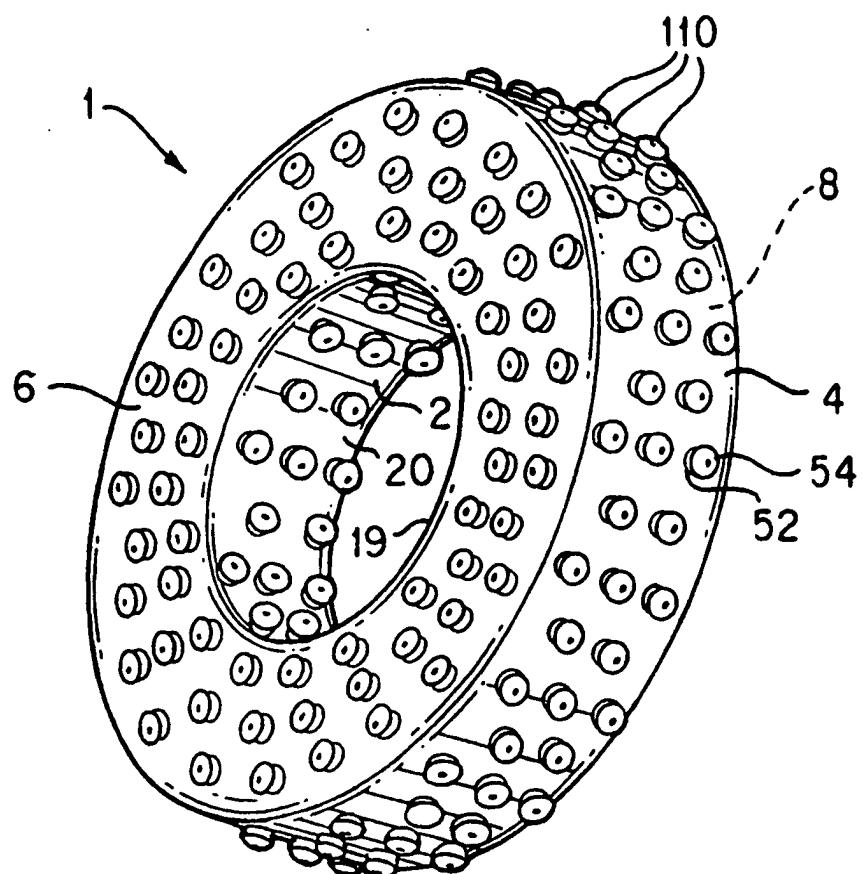


FIG. 6

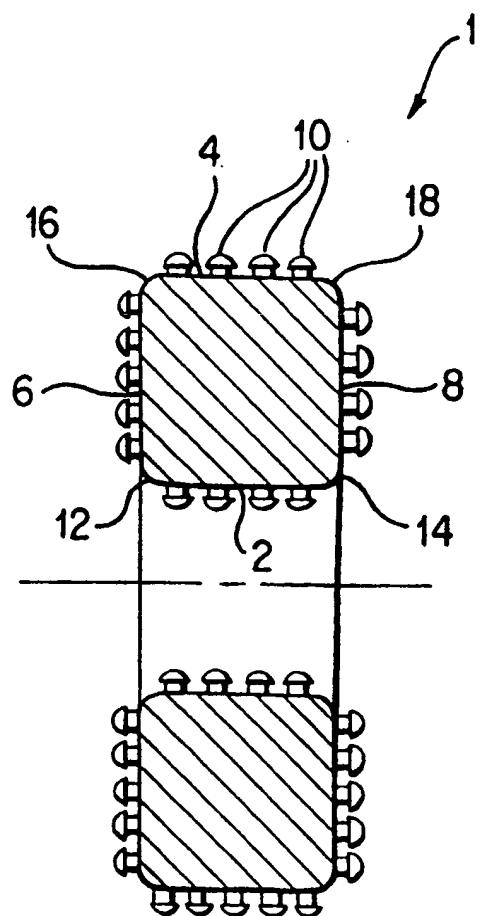


FIG. 7

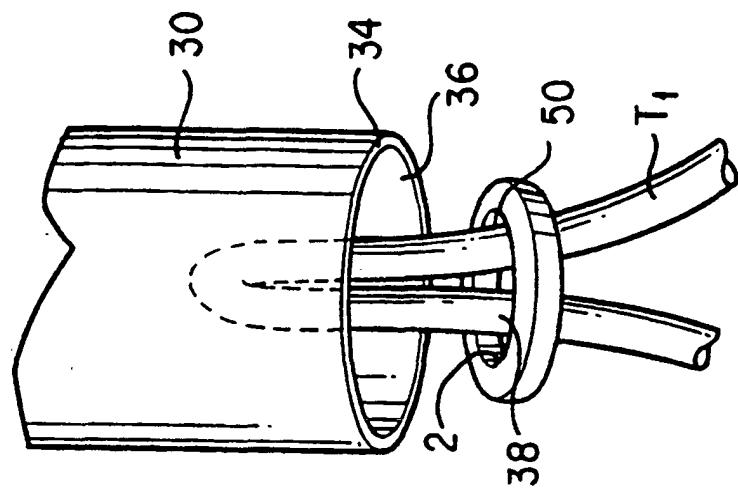


FIG. 9

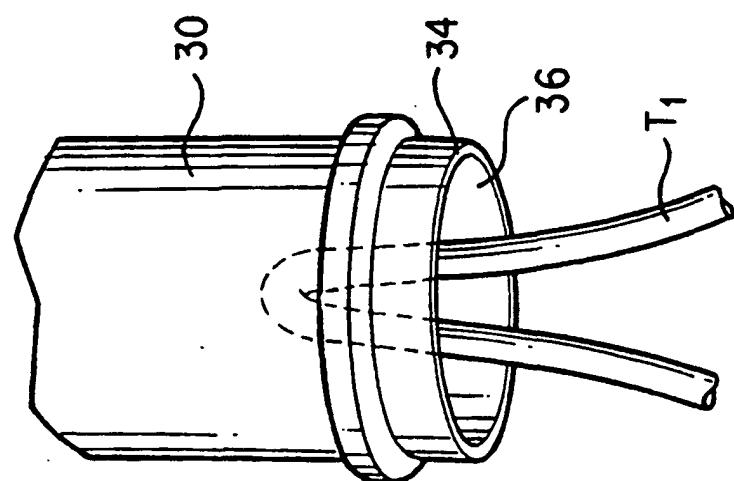


FIG. 8